

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bal Ram Singh et al.                      Art Unit : 1656  
Patent No. : 7,431,935                                      Examiner : Chih Min Kam  
Issue Date : October 7, 2008                              Conf. No. : 3757  
Serial No. : 10/766,283  
Filed : January 27, 2004  
Title : NOVEL PROTEINS WITHIN THE TYPE E BOTULINUM NEUROTOXIN  
COMPLEX

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)**

Applicants hereby petition for reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent application. The Issue Notification mailed September 17, 2008, for the above-referenced application indicates that the Patent Term Adjustment at issuance is 259 days. Reconsideration of the Patent Term Adjustment calculation to increase PTO Delay from 443 days to 805 days, and to increase Total PTA from 259 to 621 days, is respectfully requested.

**REVIEW OF PATENT TERM ADJUSTMENT CALCULATION**

A review of the Patent Term Adjustment History in the PAIR system shows that the United States Patent and Trademark Office (PTO) calculated the Patent Term Adjustment (PTA) as follows:

- 1) The PTO mailed a delayed 14-month first non-final Office Action on March 24, 2006, thereby according a PTO Delay of 362 days. Applicants do not dispute herein the patent term adjustment calculation for this PTO "A Delay."
- 2) Applicants submitted a Response to the above-referenced non-final Office Action on July 24, 2006. The PAIR system indicates the PTO received the Response on July 24, 2006, thereby according an Applicant Delay of 30 days. Applicants do not dispute herein the patent term adjustment calculation for this Applicant Delay.

**CERTIFICATE OF MAILING BY EFS-WEB FILING**

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: December 5, 2008

- 3) The PTO mailed a subsequent non-final Office Action on August 22, 2006, to which Applicants submitted a Response on February 22, 2007. The PAIR system indicates the PTO received the Response on February 22, 2007, thereby according an Applicant Delay of 92 days. Applicants do not dispute herein the patent term adjustment calculation for this Applicant Delay.
- 4) The PTO mailed a final Office Action on June 12, 2007. Applicants submitted a Notice of Appeal on November 13, 2007. The PAIR system indicates the PTO received the Notice of Appeal on November 13, 2007, thereby according an Applicant Delay of 62 days. Applicants do not dispute herein the patent term adjustment calculation for this Applicant Delay.
- 5) The application was filed on January 27, 2004 and the patent issued on October 7, 2008, more than three years later. The earliest Request for Continued Examination was filed on April 14, 2008. Only 81 days of PTO delay were calculated for issuance of the patent after three years from filing. Applicants respectfully submit that the PTO's calculation of this PTO "B Delay" contains an error and that the correct PTO Delay for issuance beyond three years from filing is 443 days, as outlined further below.

### **REMARKS**

Applicants have calculated the PTA in accordance with the clear intent of Congress. As outlined in *Wyeth v. Dudas* (*Wyeth et al. v. Jon W. Dudas*, U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), the only way that periods of time can “overlap” is if they occur on the same day, and if an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. “A Delays” are defined as delays by the Office under 35 U.S.C. 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the Office under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than 3-year application pendency.

The PTA for the instant patent, as currently calculated and shown on the face of the patent, relies on the premise that the application was delayed under § 154(b)(1)(B) before the initial three-year period expired.

The *Wyeth* court determined that this construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years,” and that “B delay” begins once the PTO has failed to issue a patent within three years, not before.

In the current PTA calculation, the Office has only given credit for the larger of “A Delay” or “B Delay,” rather than the combined sum of “A Delay” and “B Delay” (which does not include any days after three years from filing where “A” and “B” delays overlap).

In this patent, “A Delay” should be calculated as 362 days, and “B Delay” should be calculated as 443 days. Thus, the total PTO Delay should be calculated as 805 days.

In consideration of the events described above, Applicants believe the PTA calculation of 259 days is incorrect. As such, Applicants respectfully request reconsideration of the patent term adjustment in the following manner:

- 1) Total PTO Delay (including “A” and “B” Delays) should be calculated as 805 days;
- 2) Total Applicant Delay should be calculated as 184 days; and
- 3) Total PTA should be calculated as 621 days.

Applicants note that this patent is not subject to a terminal disclaimer.

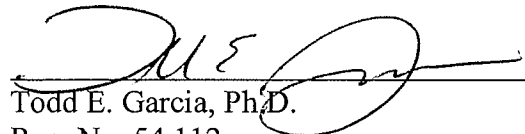
Applicant : Bal Ram Singh et al.  
Patent No. : 7,431,935  
Issued : October 7, 2008  
Serial No. : 10/766,283  
Filed : January 27, 2004  
Page : 4 of 4

Attorney's Docket No.: 08387-0002003 / UMD 96-01

The fee in the amount of \$200 required under 37 C.F.R. § 1.18(e) is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 08387-0002003.

Respectfully submitted,

Date: 12/5/08

  
Todd E. Garcia, Ph.D.  
Reg. No. 54,112

Fish & Richardson P.C.  
Customer Number 26161  
Telephone: (617) 542-5070  
Facsimile: (877) 769-7945

application for patent term adjustment.doc